

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

RECKITT BENCKISER  
PHARMACEUTICALS INC., and  
MONOSOL RX, LLC,

Plaintiffs,

v.

BIODELIVERY SCIENCES  
INTERNATIONAL, INC., and QUINTILES  
COMMERCIAL US, INC.,

Defendants.

Civil Action No.: 3:14-cv-05892-MAS-  
TJB

**ORAL ARGUMENT REQUESTED**  
**Motion Day: January 5, 2015**

**DEFENDANTS' MEMORANDUM OF LAW  
IN SUPPORT OF THEIR MOTION TO DISMISS**

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## **TABLE OF CONTENTS**

TABLE OF AUTHORITIES .....	ii
I. INTRODUCTION .....	1
II. BACKGROUND .....	1
A. The Parties .....	1
B. Plaintiffs Rushed To File This Action In Response To A Declaratory Judgment Action Filed By BDSI In The Eastern District Of North Carolina .....	2
C. Plaintiffs Fail To Plead A Claim For Indirect Infringement Against Either Defendant And Fail to Plead A Claim For Direct Infringement Against Quintiles.....	3
III. ARGUMENT .....	4
A. Standard of Review on a Motion To Dismiss.....	4
B. Plaintiffs Have Not Adequately Pled Induced Infringement Under 35 U.S.C. § 271(b) .....	5
C. Plaintiffs Have Not Adequately Pled Contributory Infringement Under 35 U.S.C. § 271(c) .....	10
D. Plaintiffs Have Not Stated A Claim For Direct Infringement By Quintiles Pursuant to 35 U.S.C. § 271(a) .....	14
IV. CONCLUSION.....	16

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>FEDERAL CASES</b>	
<i>3D Sys., Inc. v. Formlabs, Inc.</i> , No. 13 CIV. 7973, 2014 WL 1904365 (S.D.N.Y. May 12, 2014).....	7, 9
<i>Artemi Ltd. v. Safe-Strap Co.</i> , 947 F. Supp. 2d 473 (D.N.J. 2013) .....	7, 9, 12, 13, 14
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662, 129 S. Ct. 1937 (2009).....	4, 5, 7, 8, 9, 10, 12, 13, 14
<i>In re Bill of Lading Transmission &amp; Processing Sys. Patent Litig.</i> , 681 F.3d 1323 (Fed. Cir. 2012).....	4, 5, 10
<i>BioDelivery Sciences International, Inc. v. Reckitt Benckiser Pharmaceuticals, Inc., et al.</i> , C.A. No. 5:14-cv-00529-H (E.D.N.C).....	2, 3
<i>DSU Med. Corp. v. JMS Co.</i> , 471 F.3d 1293 (Fed. Cir. 2006).....	5, 8, 10
<i>Kost v. Kozakiewicz</i> , 1 F.3d 176 (3d Cir. 1993).....	4
<i>Landmark Tech. LLC v. Aeropostale</i> , No. 6:09 CV 262, 2010 WL 5174954 (E.D. Tex. Mar. 29, 2010).....	16
<i>McRo, Inc. v. Rockstar Games, Inc.</i> , No. CV 12-1513-LPS-CJB, 2014 WL 1051527 (D. Del. Mar. 17, 2014) .....	7, 8, 9
<i>MonoSol Rx, LLC v. BioDelivery Sciences International, Inc., et al.</i> , C.A. No. 3:10-cv-05695-FLW-DEA (D.N.J. filed November 2, 2010) .....	2
<i>Neology, Inc. v. Kapsch Trafficcom IVHS, Inc.</i> , Civ. No. 13-2052-LPS, 2014 WL 4675316 (D. Del. Sept. 19, 2014).....	6, 7, 8, 9
<i>Oran v. Stafford</i> , 226 F.3d 275 (3d Cir. 2000).....	2, 3
<i>Oy Ajat, Ltd. v. Vatech Am., Inc.</i> , No. CIV.A. 10-4875 PGS, 2011 WL 1458052 (D.N.J. Apr. 14, 2011).....	4, 6, 8, 9, 10
<i>PTT, LLC v. Gimme Games</i> , No. CIV.A. 13-7161 JLL, 2014 WL 5798148 (D.N.J. Nov. 6, 2014) .....	7, 8, 9, 10

<i>Reckitt Benckiser Pharmaceuticals, Inc. v. BioDelivery Sciences International, Inc.</i> , C.A. No. 5:13-760-BO (E.D.N.C. filed October 29, 2013) .....	2
<i>Richmond v. Lumisol Elec. Ltd.</i> , No. CIV.A. 13-1944 MLC, 2014 WL 1405159 (D.N.J. Apr. 10, 2014) .....	5, 15
<i>Rotec Ind., Inc. v. Mitsubishi Corp.</i> , 215 F.3d 1246 (Fed. Cir. 2000).....	16
<i>Straight Path IP Group, Inc. v. Vonage Holdings Corp.</i> , Civ. No. 14–502 (JLL), 2014 WL 3345618 (D.N.J. July 7, 2014).....	5, 6, 7, 8, 9, 10, 12, 13, 14
<i>Superior Indus., LLC v. Thor Global Enterprises Ltd.</i> , 700 F.3d 1287 (Fed. Cir. 2012).....	5, 8, 9, 12, 13, 15, 16
<i>Tellabs, Inc. v. Makor Issues &amp; Rights, Ltd.</i> , 551 U.S. 308, 127 S.Ct. 2499 (2007).....	2
<i>Xpoint Techs. v. Microsoft Corp.</i> , 730 F. Supp. 2d 349 (D. Del. 2010).....	6, 9, 11, 12, 14
<b>FEDERAL STATUTES</b>	
35 U.S.C. § 271(a) .....	14, 16
35 U.S.C. § 271(b) .....	5, 8, 10, 11, 16
35 U.S.C. § 271(c) .....	5, 10, 11, 13, 14, 16
<b>RULES</b>	
Fed. R. Civ. P. 8.....	4, 16
Fed. R. Civ. P. 12(b)(6).....	1, 2

## **I. INTRODUCTION**

Defendants Quintiles Commercial US, Inc. (“Quintiles”) and BioDelivery Sciences International, Inc. (“BDSI”) hereby move, pursuant to Fed. R. Civ. P. 12(b)(6), to dismiss patent infringement claims asserted by Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. (“RBP”) and MonoSol Rx, LLC (“MonoSol”) (collectively, “Plaintiffs”). On September 22, 2014, Plaintiffs filed the instant Complaint in the District of New Jersey against BDSI and Quintiles, following closely on the heels of a related action filed by BDSI in the Eastern District of North Carolina against Plaintiffs on September 20, 2014.

In their haste to retaliate, Plaintiffs failed to meet the heightened pleading standards required for alleging indirect infringement because their pleadings do not address each Defendant individually, do not allege all elements of the claims, and do not allege any facts making such claims plausible. Thus those claims should be dismissed against both Quintiles and BDSI. Likewise, Plaintiffs’ claims against Quintiles for direct infringement should be dismissed in their entirety because Plaintiffs fail to state a viable claim for direct patent infringement.

## **II. BACKGROUND**

### **A. The Parties**

Plaintiff RBP is part of the larger Reckitt Benckiser Group PLC, which markets, among other things, over-the-counter hygiene and medical products, household products, and various food items. In particular, RBP and Plaintiff MonoSol manufacture and sell Suboxone®, a treatment for narcotics addiction. (D.I. 1 at ¶ 3). Defendant BDSI, on the other hand, is currently launching its Bunavail™ product, an alternative treatment for opioid dependence. (D.I.

1 at ¶¶ 3-4). BDSI has a Master Services Agreement<sup>1</sup> with Quintiles to support its launch of Bunavail™. (D.I. 1 at ¶ 5). Quintiles, a contract service provider under the direction of BDSI, provides services to build awareness of the Bunavail™ product, but does not import, make, use, sell, or offer to sell the product.

**B. Plaintiffs Rushed To File This Action In Response To A Declaratory Judgment Action Filed By BDSI In The Eastern District Of North Carolina**

This litigation represents Plaintiffs' latest attempt to gain a competitive advantage over Defendant BDSI in a series of litigations between the parties. One or more Plaintiffs have filed suit alleging patent infringement by BDSI on two prior occasions: (1) *MonoSol Rx, LLC v. BioDelivery Sciences International, Inc., et al.*, C.A. No. 3:10-cv-05695-FLW-DEA (D.N.J. filed November 2, 2010) (presently stayed due to reexamination of patents-in-suit); and (2) *Reckitt Benckiser Pharmaceuticals, Inc. v. BioDelivery Sciences International, Inc.*, C.A. No. 5:13-760-BO (E.D.N.C. filed October 29, 2013) (dismissed as premature and for failure to state a claim) (the "First North Carolina Action"). After the dismissal of the First North Carolina Action, Plaintiffs promised to sue BDSI promptly upon its launch of Bunavail™.

On September 20, 2014, faced with a threat of additional litigation initiated by RBP, BDSI took matters into its own hands, and filed a declaratory judgment action in the Eastern District of North Carolina, *BioDelivery Sciences International, Inc. v. Reckitt Benckiser*

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<sup>1</sup> The Court may take judicial notice of the Master Services Agreement (Ex. A), because it was referenced by Plaintiffs in their Complaint at ¶ 5, and is filed publicly with the SEC and available on Edgar. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322, 127 S.Ct. 2499 (2007) ("courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice"); *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (taking judicial notice of properly-authenticated public disclosure documents filed with the SEC in deciding a motion for judgment on the pleadings).

*Pharmaceuticals, Inc., et al.*, C.A. No. 5:14-cv-00529-H (E.D.N.C) against Plaintiffs (the “Second North Carolina Action”). *See generally* Ex. B (Second North Carolina Action Complaint). The Second North Carolina Action seeks a declaratory judgment that U.S. Patent No. 8,475,832 – the patent asserted by Plaintiffs in the First North Carolina Action – along with U.S. Patent Nos. 7,897,080, and 8,652,378 are invalid and/or that Bunavail™ does not infringe those patents. *Id.*

Two days later, on September 22, 2014, Plaintiffs filed the instant Complaint in this District, alleging that BDSI and its contract marketing organization, Quintiles, infringed U.S. Patent No. 8,765,167 (the “’167 patent”), a patent closely related to the patents-in-suit in the Second North Carolina Action. The ’167 patent issued on July 1, 2014, and is entitled “Uniform Films for Rapid-Dissolve Dosage Form Incorporating Anti-Tacking Compositions.” As explained in the Motion to Transfer Venue filed contemporaneously with the current motion, Quintiles apparently has been brought into this lawsuit as nothing more than a jurisdictional hook. Indeed, as discussed below, the vagueness or complete omission of allegations relevant to state any claim against Quintiles makes plain that Quintiles is an afterthought to the real issues at hand.

**C. Plaintiffs Fail To Plead A Claim For Indirect Infringement Against Either Defendant And Fail to Plead A Claim For Direct Infringement Against Quintiles**

The gravamen of Plaintiffs’ Complaint is that BDSI’s Bunavail™ product will infringe the ’167 patent. A cursory review of Plaintiffs’ Complaint establishes that it is deficient in its

attempted assertion of indirect infringement claims against both Quintiles and BDSI, as well as its attempted assertion of direct infringement claims against Quintiles.<sup>2</sup>

### III. ARGUMENT

#### A. Standard of Review on a Motion To Dismiss

A court must grant a motion to dismiss when the facts stated in the complaint, taken as true and viewed in the light most favorable to the non-moving party, fail to state a claim. “While a court will accept well-pled allegations as true for the purposes of the motion to dismiss for failure to state a claim, a court will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations.” *Oy Ajat, Ltd. v. Vatech Am., Inc.*, No. CIV. A. 10-4875 PGS, 2011 WL 1458052, at \*1-2 (D.N.J. Apr. 14, 2011); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009). A party must present facts that demonstrate an entitlement to relief by outlining the elements of its claims or setting forth sufficient information to permit inferences to be drawn that the elements exist. *Oy Ajat, Ltd.*, 2011 WL 1458052, at \*1-2; *see also Kost v. Kozakiewicz*, 1 F.3d 176, 183, 187 (3d Cir. 1993) (remanding on issue of whether complaint failed to allege sufficient facts to support essential claim elements or permit inferences that elements exist). In short, the pleading must contain “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Iqbal*, 556 U.S. at 678.

Plaintiffs asserting claims for direct patent infringement must satisfy the notice requirements of Fed. R. Civ. P. 8 and Form 18, while the assertion of indirect patent infringement requires the application of the heightened *Iqbal* plausibility standard. *In re Bill of*

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<sup>2</sup> The relevant allegations of the Complaint – to the extent they exist – will be discussed in connection with the appropriate argument sections below.



*Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1336 (Fed. Cir. 2012); *Superior Indus., LLC v. Thor Global Enterprises Ltd.*, 700 F.3d 1287, 1295 (Fed. Cir. 2012).

**B. Plaintiffs Have Not Adequately Pled Induced Infringement Under 35 U.S.C. § 271(b)**

In order to properly plead a claim for induced infringement pursuant to 35 U.S.C. § 271(b), a plaintiff must satisfy the pleading standard set out in *Iqbal*. *In re Bill of Lading*, 681 F.3d at 1336. Thus, a complaint must contain facts plausibly showing that defendants knew of the patent-in-suit, specifically intended that a third party infringe the patent-in-suit, and knew that the third party's acts constituted infringement. *Id.*; *Straight Path IP Group, Inc. v. Vonage Holdings Corp.*, Civ. No. 14-502 (JLL), 2014 WL 3345618, at \*2 (D.N.J. July 7, 2014). Accordingly, inducement requires evidence supporting a specific intent to encourage another's infringement, not merely that the inducer had knowledge of the direct infringer's activities. *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006); *Richmond v. Lumisol Elec. Ltd.*, No. CIV.A. 13-1944 MLC, 2014 WL 1405159, at \*3 (D.N.J. Apr. 10, 2014) (finding that Complaint did not meet the pleading standard because it did not allege knowledge or specific intent for each defendant).<sup>3</sup>

The sole mention of induced infringement in the Complaint reads:

On information and belief, and in violation of 35 U.S.C. §§ 271(b) and/or 271(c), Defendants have indirectly infringed one or more claims of the '167 patent by inducing or contributing to the direct infringement by causing others -- specifically, for example, medical professionals and patients -- to perform acts that Defendants know will infringe one or more claims of the '167 patent.

(D.I. 1 at ¶ 25). This conclusory allegation is insufficient to state a claim for induced infringement because it fails to make allegations against each individual defendant, it fails to

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<sup>3</sup> Defendants will discuss below the import of Plaintiffs' failure to plead any allegedly wrongful conduct on the part of Quintiles separate and apart from the alleged conduct of BDSI.

allege all the elements of a claim of induced infringement, and it is not supported by facts elevating the claim from hypothetical to plausible.

The Complaint fails to allege induced infringement against either Defendant. Plaintiffs' misplaced boilerplate allegation is insufficient, *inter alia*, because it fails to allege any facts specific to Quintiles or BDSI and does not address each defendant individually. *See id.*; *see also Neology, Inc. v. Kapsch Trafficcom IVHS, Inc.*, Civ. No. 13-2052-LPS, 2014 WL 4675316, at \*7 (D. Del. Sept. 19, 2014) ("Treating these Defendants as one big group for purposes of articulating how each has encouraged the induced infringement at issue says nothing plausible as to what any particular one of them might have done") (emphasis added); *Xpoint Techs. v. Microsoft Corp.*, 730 F. Supp. 2d 349, 357 (D. Del. 2010) (directing plaintiffs to allege and specify facts supporting knowledge of the patent-in-suit for each defendant). Count I itself addresses only "Defendants," and further fails to specify any affirmative acts, knowledge, or intent related to encouraging third party infringement on the part of either Quintiles or BDSI. Without more specific information as to Plaintiffs' allegations of induced infringement against each individual defendant, Defendants are unable to respond adequately to the allegations. *See id.*

**i. Plaintiffs' Complaint Does Not Sufficiently Allege Induced Infringement Against Quintiles**

Plaintiffs' Complaint fails to allege each element of the claim of induced infringement against Quintiles. *See Straight Path*, 2014 WL 3345618, at \*2 (stating that plaintiffs must allege all elements of claim); *Oy Ajat*, 2011 WL 1458052, at \*2 (requiring allegations and facts supporting each element of indirect infringement claims). For example, Count I does not allege specifically that Quintiles knew of the '167 patent (*XPoint Techs.*, 730 F. Supp. 2d at 357), nor

does it allege Quintiles' intent to induce infringement. Indeed, there is no mention of the words "intent" or "intend" anywhere in the Complaint. Because Plaintiffs do not meet the minimal standard of setting forth each claim element against Quintiles, Plaintiffs do not satisfy the *Iqbal* standard. *See id.* at 356-367.

Even if Count I had outlined each element of an induced infringement claim against Quintiles, the Complaint still is deficient because it does not contain sufficient facts to make such a claim plausible. *See PTT, LLC v. Gimme Games*, No. CIV.A. 13-7161 JLL, 2014 WL 5798148, at \*10 (D.N.J. Nov. 6, 2014) (granting motion to dismiss because plaintiffs did not allege facts supporting claims); *Straight Path*, 2014 WL 3345618, at \*2 ("threadbare recitation of claim elements" insufficient to state a claim); *Artemi Ltd. v. Safe-Strap Co.*, 947 F. Supp. 2d 473, 481 (D.N.J. 2013) (dismissing complaint that "fails to state a claim for indirect infringement because it contains no factual allegations supporting the legal claim").

While the Complaint does describe certain promotional services allegedly performed by Quintiles, on behalf of BDSI and under the terms of the Agreement, (D.I. 1 at ¶ 5), there are no facts describing whether or how Quintiles was aware of the recently-issued '167 patent, and certainly no facts alleging that Plaintiffs put Quintiles on notice of the '167 patent. *See 3D Sys., Inc. v. Formlabs, Inc.*, No. 13 CIV. 7973, 2014 WL 1904365, at \*3-4 (S.D.N.Y. May 12, 2014) (listing facts that commonly support knowledge of a patent). Further, there are no facts describing how Quintiles would have had a sufficient understanding of the '167 patent to appreciate that others' acts may infringe it. *See Neology*, 2014 WL 4675316, at \*4 (granting motion to dismiss because Complaint did not contain any facts articulating how defendant understood the relevant technology or why it applied to defendants' products); *McRo, Inc. v. Rockstar Games, Inc.*, No. CV 12-1513-LPS-CJB, 2014 WL 1051527, at \*5 (D. Del. Mar. 17,

2014) (“A plaintiff must also allege facts plausibly showing that the defendant had knowledge that the alleged direct infringer’s acts constituted infringement”).

Indeed, separate and apart from the knowledge element, Plaintiffs provide no facts regarding Quintiles’ specific intent to induce infringement. *See Superior Indus.*, 700 F.3d at 1295-96 (“Superior does not allege any facts to support a reasonable inference that Thor specifically intended to induce infringement of the ’231 Patent or that it knew it had induced acts that constitute infringement”); *see also Straight Path*, 2014 WL 3345618, at \*2-3 (conclusory and contradictory statements fail to “satisfy the ‘rigorous’ standard of demonstrating that [Defendants] had a specific intent to encourage infringement”); *Oy Ajat*, 2011 WL 1458052, at \*2-3. The Complaint lacks any facts tending to show that Quintiles intended to perform any acts that would cause direct infringement of the ’167 patent by others, or that Quintiles intended that third parties’ actions would directly infringe the ’167 patent. *See DSU Med. Corp.*, 471 F.3d at 1305; *PTT*, 2014 WL 5798148, at \*10 (“This statement amounts to a threadbare recital of the required element and Plaintiff fails to allege any facts ... as to how Defendant actively induced a third party to perform specific acts or how Defendant specifically intended for the induced acts to infringe the patent”); *see also Neology*, 2014 WL 4675316, at \*4 (no factual specificity as to how defendants’ technology infringed the Asserted Patents, or could be used by customers to infringe plaintiffs’ intellectual property). Plaintiffs have thus failed to satisfy the *Iqbal* pleading standard for induced infringement against Quintiles. *See id.*

Plaintiffs’ incomplete allegations regarding the elements of induced infringement, devoid of supporting facts, are wholly insufficient to state a plausible claim for induced infringement against Quintiles under 35 U.S.C. § 271(b). Therefore, Defendants respectfully request that the Court dismiss Plaintiffs’ allegations of induced infringement against Quintiles with prejudice.

**ii. Plaintiffs' Complaint Does Not Sufficiently Allege Induced Infringement Against BDSI**

Plaintiffs' Complaint likewise does not allege each element of the claim of induced infringement against BDSI. *See Straight Path*, 2014 WL 3345618, at \*2; *Oy Ajat*, 2011 WL 1458052, at \*2. For example, Count I fails to allege that BDSI was aware of the '167 patent or that BDSI intended for it to be infringed. *See XPoint Techs.*, 730 F. Supp. 2d at 357. Plaintiffs correspondingly do not satisfy the *Iqbal* standard of setting forth each claim element against BDSI. *See id.*

Further, the Complaint does not contain sufficient facts to make a claim of induced infringement against BDSI plausible. *See PTT, LLC*, 2014 WL 5798148, at \*10 (dismissing claims because plaintiffs failed to allege sufficient facts); *Straight Path*, 2014 WL 3345618, at \*2 (mere recitation of elements insufficient to state a claim); *Artemi Ltd.*, 947 F. Supp. 2d at 481 (dismissing complaint that contained no factual allegations supporting the legal claim).

While the Complaint does allege that BDSI performed marketing and sales activities, it does not indicate how BDSI became aware of the recently-issued '167 patent, or understood the patent sufficiently to have knowledge that others' activities infringed it. *See 3D Sys., Inc.*, 2014 WL 1904365, at \*3-4 (listing facts that commonly support knowledge of a patent); *Neology*, 2014 WL 4675316, at \*4 (dismissing claims that were not supported by facts describing defendant's understanding of the patent or its application to accused products); *McRo, Inc.*, 2014 WL 1051527, at \*5 ("A plaintiff must also allege facts plausibly showing that the defendant had knowledge that the alleged direct infringer's acts constituted infringement").

Likewise, the Complaint provides no facts regarding BDSI's specific intent to induce infringement. *See Superior Indus.*, 700 F.3d at 1295-96 (dismissing Complaint that was devoid

of facts supporting defendant's intent to induce infringement); *see also Straight Path*, 2014 WL 3345618, at \*2-3 (contradictory and conclusory statements insufficient to demonstrate intent); *Oy Ajat*, 2011 WL 1458052, at \*2-3. Plaintiffs allege no facts that plausibly demonstrate that BDSI intended its own actions to induce third party infringement, or intended that others' actions would directly infringe the '167 patent. *See DSU Med. Corp.*, 471 F.3d at 1305; *PTT*, 2014 WL 5798148, at \*10 (threadbare recital of element of intent without supporting facts insufficient to allege specific intent).

Plaintiffs' incomplete allegations regarding the elements of induced infringement, devoid of supporting facts, are wholly insufficient to state a plausible claim for induced infringement against BDSI under 35 U.S.C. § 271(b). Therefore, Defendants respectfully request that the Court also dismiss Plaintiffs' allegations of induced infringement against BDSI with prejudice.

**C. Plaintiffs Have Not Adequately Pled Contributory Infringement Under 35 U.S.C. § 271(c) Against Either Quintiles Or BDSI**

As with induced infringement, in order to properly plead a claim for contributory infringement pursuant to 35 U.S.C. § 271(c), a plaintiff must satisfy the pleading standard set out in *Iqbal*. *In re Bill of Lading*, 681 F.3d at 1336. To state a claim for contributory infringement, a plaintiff must plead facts that allow a plausible inference that the components sold or offered for sale are material to practicing the invention and have no substantial non-infringing uses, that defendants knew that the accused products were especially made or especially adapted to infringe the asserted patents, and that a third party used the accused products to directly infringe the asserted patents. *Id.* at 1337; *Straight Path*, 2014 WL 3345618, at \*3.

Here again, Plaintiffs fail to meet their pleading burden. The Complaint is conclusory and insufficient to state a claim for contributory infringement because it fails to make allegations against each individual defendant, it fails to allege all elements of a claim of contributory infringement, and it is not supported by relevant facts. The minimal allegations of the Complaint state:

On information and belief, and in violation of 35 U.S.C. §§ 271(b) and/or 271(c), Defendants have indirectly infringed one or more claims of the '167 patent by inducing or contributing to the direct infringement by causing others -- specifically, for example, medical professionals and patients -- to perform acts that Defendants know will infringe one or more claims of the '167 patent...

On information and belief, Defendants know (a) that the Bunavail™ product is especially made or adapted for use in infringing one or more claims of the '167 patent and (b) that the Bunavail™ product is not suitable for any substantial noninfringing use.

(D.I. 1 at ¶¶ 25-26).

As discussed below, the above allegations fall short of the relevant pleading standard in every regard. First, Plaintiffs' allegation of contributory infringement is insufficient because it does not address either Defendant individually. *See Xpoint Techs.*, 730 F. Supp. 2d at 357 (directing plaintiffs to allege and specify facts supporting knowledge of the patent-in-suit for each defendant). Second, Plaintiffs do not specify any affirmative acts, knowledge, or intent on the part of either Quintiles or BDSI that relate to providing "components" which are then used in an allegedly infringing product or manner. Without more specific information regarding each individual defendant's activities that allegedly constitute contributory infringement, Defendants are unable to respond adequately to the claim. *See id.*

**i. Plaintiffs' Complaint Does Not Sufficiently Allege  
Contributory Infringement Against Quintiles**

Plaintiffs' Complaint also fails to allege each element of the claim of contributory infringement against Quintiles. *See Superior Indus.*, 700 F.3d at 1296 (dismissing complaint that failed to allege all elements of contributory infringement); *Straight Path*, 2014 WL 3345618, at \*3 (requiring allegations and facts supporting each element of indirect infringement claims). For example, the Complaint is completely devoid of any allegations regarding Quintiles' intent, Quintiles' sale of or offer to sell "components" of an allegedly infringing product, and Quintiles' specific knowledge of the '167 patent. By failing to plead each claim element against Quintiles, Plaintiffs do not meet the *Iqbal* standard. *See id.*

Moreover, Plaintiffs' Complaint does not allege any requisite supporting facts that would make a claim of contributory infringement against Quintiles plausible. *See Straight Path*, 2014 WL 3345618, at \*3 (threadbare recitation of claim elements insufficient to state a claim); *Artemi*, 947 F. Supp. 2d at 481 (dismissing complaint that "fails to state a claim for indirect infringement because it contains no factual allegations supporting the legal claim"). For example, although Plaintiffs allege facts regarding certain promotional activities by Quintiles on behalf of BDSI, there are no facts describing how Quintiles became aware of the '167 patent, nor that it had knowledge third parties were infringing that patent.

Further, the Complaint contains no facts describing how Quintiles would "make, use, sell, or import components [d]efendant know[s] to be especially adapted for use in infringing the ['167] patent." *XPoint Techs.*, 730 F. Supp. 2d at 356 (emphasis added); *see also Artemi*, 947 F. Supp. 2d at 481 ("Artemi does not plead any facts concerning which "component" of the Spacemaker Safe-Strap has sold or offered to sell within the United States, nor does it plead that



Safe-Strap acted with the requisite intent”). Indeed, the word “component” does not appear anywhere in the Complaint. Similarly, Plaintiffs allege no facts suggesting that Quintiles had the requisite intent for contributory infringement. *See Straight Path*, 2014 WL 3345618, at \*4 (mere speculation on the issue of intent, concerning awareness of patent, insufficient to survive a motion to dismiss). Accordingly, Plaintiffs fail to satisfy the *Iqbal* standard. *Id.*

Plaintiffs have failed to allege all elements of a claim for contributory infringement against Quintiles under 35 U.S.C. § 271(c), and further have failed to provide any facts that would make such a claim against Quintiles plausible. Therefore, Quintiles respectfully requests that the Court dismiss Plaintiffs’ allegations of contributory infringement with prejudice.

**ii. Plaintiffs’ Complaint Does Not Sufficiently Allege  
Contributory Infringement Against BDSI**

Plaintiffs’ Complaint likewise does not allege each element of the claim of contributory infringement against BDSI. *See Superior Indus.*, 700 F.3d at 1296; *Straight Path*, 2014 WL 3345618, at \*3. For example, the Complaint does not contain any allegations regarding BDSI’s intent, any BDSI “components” constituting a material part of an allegedly infringing product, or BDSI’s specific knowledge of the ’167 patent. Plaintiffs thus do not meet the *Iqbal* standard requiring pleading of each claim element. *See id.*

Moreover, Plaintiffs allege no supporting facts that would make a claim of contributory infringement against BDSI plausible. *See Straight Path*, 2014 WL 3345618, at \*3 (threadbare recitation of claim elements without supporting facts insufficient to state a claim); *Artemi*, 947 F. Supp. 2d at 481 (dismissing complaint with insufficient factual support). For example, although Plaintiffs allege facts regarding certain sales and marketing activities by BDSI, there are no facts

describing its knowledge of the '167 patent, nor that it was aware of any third party infringement of the patent.

Further, the Complaint contains no facts describing “components” that BDSI makes, uses, sells or imports and “know[s] to be especially adapted for use in infringing the ['167] patent.” *XPoint Techs.*, 730 F. Supp. 2d at 356; *see also Artemi*, 947 F. Supp. 2d at 481 (dismissing contributory infringement claims because plaintiff did not plead facts regarding components). Similarly, Plaintiffs fail to allege facts supporting any intent on the part of BDSI to contribute to infringement. *See Straight Path*, 2014 WL 3345618, at \*4 (mere speculation of intent insufficient for claims to survive). Accordingly, Plaintiffs fail to satisfy the *Iqbal* standard. *Id.*

Plaintiffs have failed to allege all elements of a claim for contributory infringement against BDSI under 35 U.S.C. § 271(c), and further have failed to provide any facts that would make such a claim against BDSI plausible. Therefore, Defendants respectfully request that the Court dismiss Plaintiffs’ allegations of contributory infringement against BDSI with prejudice.

**D. Plaintiffs Have Not Stated A Claim For Direct Infringement By Quintiles Pursuant to 35 U.S.C. § 271(a)**

Plaintiffs’ Complaint alleges that BDSI sought and obtained FDA approval to market Bunavail™, and that it is in the midst of its commercial launch of Bunavail™. (D.I. 1 at ¶¶ 3-4). The Complaint also alleges that BDSI has manufactured (or had manufactured), offered for sale, and/or is in the process of selling, Bunavail™. *Id.* ¶ 6. While those allegations may be sufficient to state a claim for direct infringement against BDSI, they are not sufficient to state a claim for direct infringement against Quintiles, and in fact, belie such a claim against Quintiles.

Accepting as true the allegations in the Complaint, only BDSI makes and sells Bunavail™, and it has contracted with Quintiles for marketing activities, *i.e.*, “supporting the recruitment, training and deployment of a sales force to market Bunavail™.” (D.I. 1 at ¶¶ 5, 20-21). The Complaint does not allege that Quintiles manufactures or uses Bunavail™. Further, there are no facts suggesting that Quintiles has engaged in activity that constitutes a sale or an offer to sell under the contractual principles that govern direct infringement: namely, the Complaint is devoid of allegations of communication of a “manifestation of willingness to enter into a bargain,”<sup>4</sup> communication of price, or acceptance and consideration from a third party. *See Superior Indus.*, 700 F.3d at 1294-95. Indeed, the Complaint contradicts any allegation that Quintiles is actually making, using, selling or offering Bunavail™ for sale, because the Complaint makes clear that BDSI will distribute Bunavail™ from 115 distribution centers ((D.I. 1 at ¶ 20) to wholesalers (*id.*), that BDSI’s “major wholesaler contracts are finalized” (*id.*), that BDSI has a pharmacy stocking program (*id.*), and that “BDSI had ‘released and published the price of Bunavail™[.]’” *Id.* (emphasis added). Quintiles, on the other hand, is not included in the allegations of the specific activities that would implicate the actual sales or offers to sell that are required for direct infringement.

Accordingly, while the Complaint may include allegations sufficient to state a claim for direct infringement against BDSI, it fails to do so against Quintiles. As with Plaintiffs’ failed allegations of indirect infringement, Plaintiffs cannot simply lump Quintiles and BDSI together for purposes of pleading direct infringement claims. *See Richmond*, 2014 WL 1405159, at \*3 (pleading with single count that lumped direct and indirect infringement claims and different

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<sup>4</sup> An offer to sell is a “manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it.” Restatement (Second) of Contracts § 24 (1981).

defendants together failed to give each defendant adequate notice under FRCP 8); *Landmark Tech. LLC v. Aeropostale*, No. 6:09 CV 262, 2010 WL 5174954, at \*3-4 (E.D. Tex. Mar. 29, 2010) (“While Form 18 does not set a high bar for what must be alleged, Landmark has not met that bar. The Court has high expectations of a plaintiff’s preparedness before it brings suit”). Plaintiffs have wholly failed to allege that Quintiles makes or uses (much less possesses) Bunavail™, and the activities that Quintiles is alleged to have participated in do not constitute sales or offers for sales within the meaning of 35 U.S.C. § 271(a). *See Superior Indus.*, 700 F.3d at 1294-95 (sales and offers for sales are defined under traditional contract law principles for purposes of 271(a)); *Rotec Ind., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1254–55 (Fed. Cir. 2000) (defining § 271(a)’s “offer to sell” liability according to the norms of traditional contractual analysis).

For these reasons, Defendants respectfully request that the claims against Quintiles for direct infringement pursuant to 35 U.S.C. § 271(a) be dismissed with prejudice.

#### **IV. CONCLUSION**

For the reasons set forth above, Defendants respectfully request that the Court: (1) dismiss with prejudice Plaintiffs’ purported claims against BDSI of induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c); and (2) dismiss with prejudice Plaintiffs’ purported claims against Quintiles of induced infringement under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and direct infringement under 35 U.S.C. § 271(a).

Dated: December 12, 2014

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing notice and supporting documents were served by electronically filing the same with the Court's CM/ECF system, which caused a Notice of Electronic Filing to be emailed to the following:

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